



Nutrition and Health Group

The essential ingredient™

May 29, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

To the Food and Drug Administration:

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21. U.S.C. § 343 (r)(6), we hereby notify FDA that the Henkel Corporation has included the following statement in labeling for a dietary ingredient that it manufactures and markets for use in dietary supplement products.

The following information is provided:

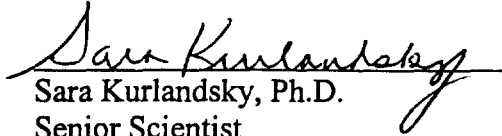
1. The name and address of the manufacturer and distributor of the dietary ingredient is as follows: Henkel Corporation, 5325 South 9th Avenue, LaGrange, Illinois 60525-3602.
2. The text of the labeling statement is as follows:

Pycnogenol® is a dietary ingredient that helps maintain normal healthy cell function by protecting against free radical activity.
3. The name of the dietary ingredient that is the subject of the statement is as follows: Pycnogenol®; French maritime pine bark extract (*Pinus maritima*; *Pinus pinaster*).
4. We do not manufacture or distribute retail dietary supplement products but only bulk dietary ingredients used by others in their manufacture of their dietary supplements. The information provided above relates to the labeling that will be used by the Henkel Corporation and for which the Henkel Corporation is responsible.

We trust this provided the information that is needed. If you should have any questions, please just let us know.

Pursuant to FDA regulations concerning "notification procedures for certain types of statements on dietary supplements," 21 C.F.R. § 101.93(a)(3), I certify that, to the best of my knowledge and in my opinion, the information contained in this notice is complete and accurate, and that the Henkel Corporation has substantiation that the statement is truthful and not misleading.

Sincerely yours,

A handwritten signature in cursive script, reading "Sara Kurlandsky", written over a horizontal line.

Sara Kurlandsky, Ph.D.

Senior Scientist

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